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*Document Management Branch HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852*


RE: Docket No. 97N-484S (FDA Proposal to Regulate Allograft Tissue)

Dear Sirs:

It has come to my attention that the FDA is proposing regulation of allograft tissue. I further understand that the FDA plans to regulate allograft tissue as medical devices.

I would totally disagree with this approach. The bone banks that I currently use are all approved by The American Association of Tissue Banks. There are very rigid requirements for procurement and processing of the bone. I see no indication that the FDA needs to regulate the use of allograft tissue. We certainly have enough documentation over the last 35 to 40 years that allograft bone is safe and efficacious. As a consultant to the FDA Orthopedic and Rehabilitation Panel I would vote against FDA regulation of allograft tissue.

Sincerely,

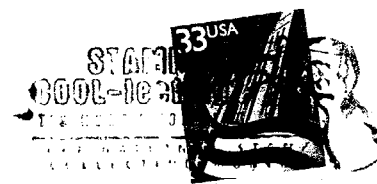

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